

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Re: Appeal to the Board of Patent Appeals and Interferences

Appellants	Kaylor et al.)	Examiner:	Lyle Alexander
)		
Serial Number:	10/035,013)	Group Art Unit:	1797
)		
Filed:	December 24, 2001)	Customer Number:	22827
)		
Confirmation No:	1072)	Deposit Account:	04-1403
)		
Title:	Reading Device, Method, and System for Conducting Lateral Flow Assays)	Attorney Docket No.	KCX-461 (15790)
)		

1. ☐ **NOTICE OF APPEAL:** Pursuant to 37 CFR 41.31, Applicant hereby appeals to the Board of Appeals from the decision dated _____ of the Examiner twice/finally rejecting claims _____.
2. ☒ **BRIEF** on appeal in this application pursuant to 37 CFR 41.37 is transmitted herewith (1 copy).
3. ☐ An **ORAL HEARING** is respectfully requested under 37 CFR 41.47 (due within two months after Examiner's Answer).
4. ☐ Reply Brief under 37 CFR 41.41(b) is transmitted herewith (1 copy).
5. ☐ "Small entity" verified statement filed: [] herewith [] previously.

6. **FEE CALCULATION:**

	Fees
If box 1 above is X'd enter \$ 540.00	\$ <u>0.00</u>
If box 2 above is X'd enter \$ 540.00	\$ <u>540.00</u>
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If box 4 above is X-d enter -0- (no fee)	\$ <u>0.00</u>

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\$ 130.00

SUBTOTAL: \$ 670.00

Less any previous extension fee paid since above original due date. - \$ 0.00

Less any previous fee paid for prior Notice of Appeal since Board did not render a decision on the merits. MPEP § 1204.01 - \$ 0.00

Less any previous fee paid for submitting Brief on prior Appeal since Board did not render a decision on the merits. MPEP § 1204.01 - \$ 0.00

SUBTOTAL: \$ 670.00

If "small entity" verified statement filed ☐ previously,
☐ herewith, enter one-half (1/2) of subtotal and subtract - \$ 0.00

TOTAL FEE ENCLOSED: \$ 670.00

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- ☐ Charge fee to our Deposit Account/Order Nos. in the heading hereof (for which purpose one additional copy of this sheet is attached)
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- ☐ Fee NOT required since paid in prior appeal in which the Board of Appeals did not render a decision on the merits.

The Commissioner is hereby authorized to charge any fee specifically authorized hereafter, or any fees in addition to the fee(s) filed, or asserted to be filed, or which should have been filed herewith or concerning any paper filed hereafter, and which may be required under Rules 16-18 (deficiency only) now or hereafter relative to this application and the resulting official document under Rule 20, or credit any overpayment, to our Account No. shown in the heading hereof. This statement does not authorize charge of the issue fee in this case.

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Date: October 21, 2008

I hereby certify that this correspondence and all attachments and any fee(s) are being electronically transmitted via the internet to the U.S. Patent and Trademark Office using the Electronic Patent Filing System on October 21, 2008.

Sandra S. Perkins

(Typed or printed name of person transmitting documents)



(Signature of person transmitting documents)

PATENT
ATTORNEY DOCKET NO: KCX-461 (15790)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application: Kaylor et al.)	Examiner: Lyle Alexander
)	
Serial No: 10/035,013)	Art Unit: 1797
)	
Filed: December 24, 2001)	Confirmation No: 1072
)	
Title: Reading Device, Method, and)	Deposit Account No: 04-1403
System for Conducting Lateral)	
Flow Assays)	Customer No: 22827

Honorable Commissioner for Patents
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

BRIEF ON APPEAL

Honorable Commissioner:

Appellants submit the following brief on appeal in accordance with 37 C.F.R. §
41.37:

1. REAL PARTY IN INTEREST

The real party in interest in this matter is the assignee of record, Kimberly-Clark
Worldwide, Inc.

2. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to the Appellants or the
Appellants' legal representative which will directly affect or be directly affected by or
have a bearing on the Board's decision in the pending appeal.

3. STATUS OF CLAIMS

Claims 62-64, 66, and 69-80, including independent claim 62, were finally rejected under 35 U.S.C. § 102(b) in the Final Office Action of April 18, 2008. Claims 62-64, 66, and 69-80 are hereby appealed and attached hereto in Section 8.

4. STATUS OF AMENDMENTS

To the Appellants' knowledge, all amendments have been entered into the record.

5. SUMMARY OF CLAIMED SUBJECT MATTER

The present claims are directed to a reading device for lateral flow assays, and a system for conducting assays. (See e.g., Appl. p. 4, ll. 2-3). The reading device is configured for detecting an assay result from a membrane strip, in which the result is revealed by the binding of a detectable analyte within a detection zone along the membrane strip. (See e.g., Appl. p. 4, ll. 3-6). The assay reading device comprises a housing and a receiving port within the housing. (See e.g., Appl. p. 4, ll. 6-7). The receiving port may include a light barrier structure, and admits a membrane strip directly from the outside of the housing. (See e.g., Appl. p. 4, ll. 7-9). That is, a membrane strip is inserted into the receiving port. (See e.g., Appl. p. 4, ll. 9-10). The receiving port may be configured for minimizing the introduction of stray or ambient light into the reading device. (See e.g., Appl. p. 4, ll. 10-12).

Independent claim 62, for instance, is directed to a system for conducting a lateral flow assay to detect the presence or quantity of an analyte in a sample. The system comprises (a) a lateral flow membrane strip comprising a detection zone, wherein upon application, the sample is capable of traversing through the membrane

strip to the detection zone and (b) a reading device. (See e.g., ¶¶ [0027]-[0028] and Fig. 2). The reading device includes the following components:

(1) a “housing” within which is contained an electromagnetic radiation source and a sensor capable of detecting the intensity of electromagnetic radiation. (See e.g., ¶¶ [0027]-[0028] and Fig. 2).

(2) a “light barrier structure” positioned adjacent to an exterior surface of the housing. (See e.g., ¶ [0029] and Fig. 3). The light barrier structure defines a receiving port between a top plate and bottom plate for insertion with the membrane strip. (See e.g., ¶¶ [0029]-[0032] and Figs. 3, 3a, and 4). Further, the bottom plate of the light barrier structure defines an aperture through which electromagnetic radiation from the source is capable of passing before contacting the lateral flow membrane strip. (See e.g., ¶¶ [0029]-[0034]). The aperture approximates the size of the detection zone. (See e.g., ¶ [0034]).

(3) a “light absorbent member” positioned within the receiving port to absorb stray light, the light absorbing member comprising an absorption pad that is located adjacent to the membrane strip upon insertion into the receiving port. (See e.g., ¶¶ [0030]-[0031] and Figs. 3, 3a, and 4). The absorption pad covers an area under which the membrane strip is impacted by electromagnetic radiation. (See e.g., ¶¶ [0030]-[0031] and Figs. 3, 3a, and 4).

6. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

In the Final Office Action, 62-64, 66, and 69-80 were rejected under 35 U.S.C. § 102(b) as being unpatentable over EP 0308770 or U.S. Patent No. 4,833,088, both to DeSimone, et al.¹

7. ARGUMENT

Appellants respectfully submit that the presently pending claims are patentable over the cited references.

I. Independent Claim 62 is Not Anticipated by DeSimone, et al. Under 35 U.S.C. § 102(b)

To demonstrate anticipation under § 102, the four corners of a single, prior art reference must describe every limitation of the claimed invention. *Xerox Corp. v. 3Com Corp.*, 458 F.3d 1310, 1322 (Fed. Cir. 2006); *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000). Furthermore, the prior art reference must not only disclose all limitations of the claim within the four corners of the document, but must also disclose those limitations arranged or combined in the same way as recited in the claims, not merely in a particular order. *Net MoneyIn v. Verisign*, No. 2007-1565 (Fed. Cir. Oct. 20, 2008); *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983).

In this case, the Examiner asserts that DeSimone, et al. anticipates independent claim 62 under 35 U.S.C. § 102. DeSimone, et al. is generally directed to a reflectance photometer that employs a positive, snap action reagent strip handling mechanism. (Col. 5, ll. 19-20). As shown in Figs. 1-5, the reflectance photometer 10 of DeSimone,

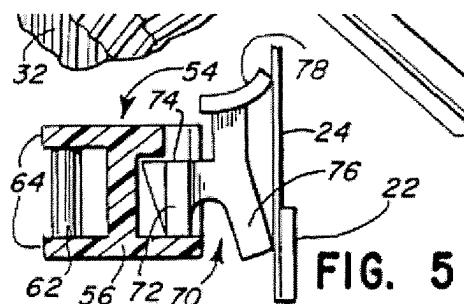
¹ EP0308770 is the European counterpart to U.S. Patent No. 4,833,088 to DeSimone, et al. Thus, for the sake of convenience and to simplify the issues on appeal, the present appeal brief makes reference to the U.S. patent.

et al. includes a reagent strip handling mechanism 26 for loading, holding and measuring a reagent strip 24 and a reagent pad 22. According to DeSimone, et al., the slide assembly 30 moves with positive, snap action between a closed measuring position (Fig. 2) and an open loading position (Fig. 3) to minimize the possibility that it moves to an intermediate position between the positions and results in an inaccurate measurement. (Col. 5, ll. 34-49).

Appellants submit, however, that DeSimone, et al. does not disclose each and every limitation of independent claim 62, much less those limitations arranged in the same manner as claimed.

A. DeSimone, et al. Does Not Disclose the Claimed “Absorption Pad”

Independent claim 62 requires a light absorbent member that is positioned within the receiving port to absorb stray light. The light absorbing member comprises an “absorption pad” that is located adjacent to the membrane strip upon insertion into the receiving port and covers an area under which the membrane strip is impacted by electromagnetic radiation. According to the Examiner, the claimed “absorption pad” is satisfied by the light seal 70 of DeSimone, et al. The light seal 70 is fabricated of a resilient elastomer (e.g., silicone rubber) allowing it to flex to provide a biased on the reagent strip and pad 22 during measurement. (Col. 7, ll. 33-38). The light seal 70 is best shown in Fig. 5, which is re-produced below.



As shown, the seal 70 includes a first arm 76 that extends through an opening 52 between flanges 48 and 50 in the measurement position to engage a reagent strip 24 behind the reagent pad 22. The seal 70 also includes a second arm or shield 78 that engages the reagent strip 24 above the reagent pad 22. Due to its width, the shield 78 can engage both sides of the reagent strip 24 in the loading position and thereby provide a seal against ambient light and dust. (Col. 7, ll. 39-55). Although DeSimone, et al. does indicate that the shield 78 seals against ambient light, it does not *cover an area under which the membrane strip is impacted by electromagnetic radiation* as required by independent claim 62.

To better understand this feature of independent claim 62, reference is made to Fig. 4 of the present application, which is re-produced in part below.

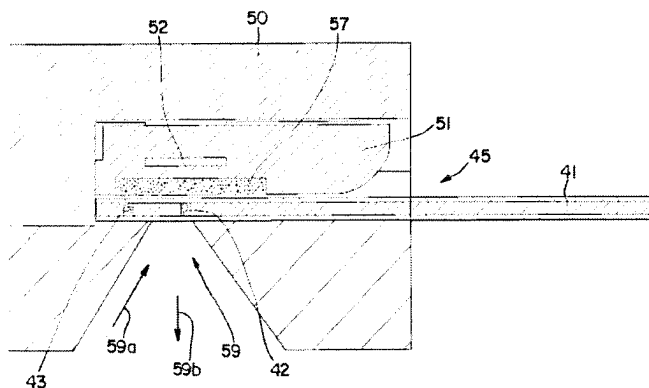
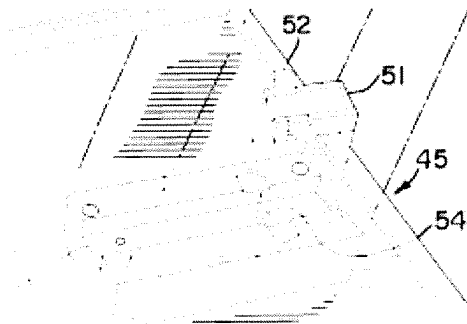


FIG. 4

As shown, a light absorbing member 57 is positioned so that it covers an area under which the membrane strip 41 is impacted by electromagnetic radiation 59. In this manner, the light absorbing member 57 can prevent light from being reflected back to a sensor, thereby improving the sensitivity of the reading. The shield 78 of DeSimone, et al. does not act as an absorption pad covering the area of the strip which is impacted by light as required by independent claim 62.

B. DeSimone, et al. Does Not Disclose the “Aperture” of the Claimed “Light Barrier Structure”

Independent claim 62 also requires a “light barrier structure” that comprises a top plate and a bottom plate. The bottom plate defines an “aperture” through which electromagnetic radiation from the source is capable of passing before contacting the lateral flow membrane strip. The *aperture has a size that approximates the size of the detection zone*. In Fig. 3 of the present application (which is re-produced in part below), for instance, a light barrier structure 28 is shown that includes a bottom plate 56, which defines an aperture 54 having a size that approximates the size of the detection zone of the membrane strip (See e.g., Fig. 2).



DeSimone, et al. indicates that an aperture is formed in the bottom 44 of slide housing 34 between flanges 48 and 50. When a reagent strip 24 is placed in the holding section 51, the reagent pad 22 is positioned on and over the aperture. Further,

when the slide assembly 30 is moved to the measurement position (Fig. 2), the aperture and the reagent pad 22 are positioned over and adjacent to the read head to allow measurement of the color developed in the pad 22 and to allow a user to check the position of the reagent pad 22 in the loading position (Fig. 3) to ensure that it is properly positioned in the holding section 51. (Col. 6, ll. 16-32). DeSimone, et al. does not teach, however, that the *aperture has a size that approximates the size of the detection zone* as required by independent claim 62.

II. Dependent Claim 71 is Not Anticipated by DeSimone, et al. Under 35 U.S.C. § 102(b)

Dependent claim 71 requires that a capture reagent (e.g., antibody) is immobilized within the detection zone that is configured to directly or indirectly bind to the analyte. As explained in the present application, the capture reagent may capture probe complexes used in the assay. (See e.g., ¶ [0047]-[0064]). To the contrary, DeSimone, et al. simply employs a substance that can react with an indicator to turn it a different shade of color. (Col. 1, ll. 49-58). DeSimone, et al. does not, however, disclose a capture reagent immobilized within the detection zone that is configured to directly or indirectly bind to the analyte.

III. Dependent Claim 72 is Not Anticipated by DeSimone, et al. Under 35 U.S.C. § 102(b)

Dependent claim 72 requires that the aperture defined by the light barrier structure is elongated. DeSimone, et al. does not disclose an aperture of this configuration.

IV. Dependent Claim 73 is Not Anticipated by DeSimone, et al. Under 35 U.S.C. § 102(b)

Dependent claim 73 requires that the aperture defined by the light barrier structure is circular. DeSimone, et al. does not disclose an aperture of this configuration.

V. Dependent Claims 79 and 80 are Not Anticipated by DeSimone, et al. Under 35 U.S.C. § 102(b)

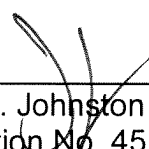
In addition to the membrane strip of independent claim 62, dependent claim 79 further requires a *sample pad* in fluid communication with the membrane strip that defines the point of application for the sample, and dependent claim 80 requires a *wicking pad* in fluid communication with the membrane strip. As explained in the present application, the wicking pad “pulls” the liquid containing the analyte along the membrane from one end to another end. (See e.g., ¶ [0045]). DeSimone, et al. describes a reagent pad located on a reagent strip, but does not expressly disclose the claimed sample pad or wicking pad. Even assuming *arguendo* that the reagent pad can be considered a “wicking pad”, DeSimone, et al. nevertheless fails to disclose the sample pad of dependent claim 79.

In conclusion, it is respectfully submitted that the claims are patentably distinct over the prior art of record and that the present application is in complete condition for allowance. As such, Appellants respectfully request issuance of the patent.

Respectfully submitted,

DORITY & MANNING,
ATTORNEYS AT LAW, P.A.

10/21/08
Date



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8. CLAIMS APPENDIX

62. (Rejected) A system for conducting a lateral flow assay to detect the presence or quantity of an analyte in a sample, the system comprising:

(a) a lateral flow membrane strip comprising a detection zone, wherein upon application, the sample is capable of traversing through the membrane strip to the detection zone; and

(b) a reading device comprising:

(i) a housing within which is contained an electromagnetic radiation source and a sensor capable of detecting the intensity of electromagnetic radiation, wherein the electromagnetic radiation source and sensor are positioned so that electromagnetic radiation emitted from the source is capable of being reflected from the lateral flow membrane strip to the sensor, the housing having an exterior surface;

(ii) a light barrier structure comprising a top plate and a bottom plate, the bottom plate being positioned adjacent to the exterior surface of the housing, wherein a receiving port is defined between the top plate and the bottom plate, the lateral flow membrane strip being capable of insertion into the receiving port, wherein the bottom plate defines an aperture through which electromagnetic radiation from the source is capable of passing before contacting the lateral flow membrane strip, the aperture having a size that approximates the size of the detection zone; and

(iii) a light absorbing member positioned within the receiving port to absorb stray light, the light absorbing member comprising an absorption pad that is located adjacent to the membrane strip upon insertion into the receiving port, the absorption

pad covering an area under which the membrane strip is impacted by electromagnetic radiation.

63. (Rejected) The system of claim 62, further comprising a pressure plate that is positioned in the receiving port between the top plate and the bottom plate for bearing against the lateral flow membrane strip upon insertion.

64. (Rejected) The system of claim 63, wherein the pressure plate is spring loaded.

65. (Cancelled)

66. (Rejected) The system of claim 62, wherein the light-absorbing member comprises a flexible material.

67-68. (Cancelled)

69. (Rejected) The system of claim 62, wherein the receiving port defines a first stop position for a reference reading and a second stop position for a sample reading.

70. (Rejected) The system of claim 69, wherein one or more of the stop positions is formed by notches in the bottom plate.

71. (Rejected) The system of claim 62, wherein a capture reagent is immobilized within the detection zone, the capture reagent being configured to directly or indirectly bind to the analyte.

72. (Rejected) The system of claim 62, wherein the aperture is elongated.

73. (Rejected) The system of claim 62, wherein the aperture is circular.

74. (Rejected) The system of claim 62, wherein the area of the aperture is 1.8 times or less than the area of the detection zone.

75. (Rejected) The system of claim 62, wherein the area of the aperture is 1.3 times or less than the area of the detection zone.

76. (Rejected) The system of claim 62, wherein the electromagnetic radiation source comprises a light emitting diode.

77. (Rejected) The system of claim 62, wherein the sensor comprises a photodiode.

78. (Rejected) The system of claim 62, further comprising a display for providing results of the assay.

79. (Rejected) The system of claim 62, further comprising a sample pad in fluid communication with the membrane strip, the sample pad defining the point of application for the sample.

80. (Rejected) The system of claim 62, further comprising a wicking pad in fluid communication with the membrane strip.

81. (Cancelled)

9. EVIDENCE APPENDIX

None

10. **RELATED PROCEEDINGS APPENDIX**

None